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| 40518 | 7590 | 08/30/2010 | EXAMINER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/734,562 | MICHLITSCH ET AL. |
| | Examiner | Art Unit |
| | DIANNE DORNBUSCH | 3773 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 June 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 21-23, 25, 43-45, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortenbach et al. (7,232,445) in view of Crockard (5,174,276).

Claims 21 and 43:

Kortenbach discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Col. 1 Lines 32-36), the method comprising: advancing an overtube (100 and 104) within the hollow body organ in a flexible state (Col. 7 Lines 50-53); transitioning the overtube to a desired configuration (Fig. 10); advancing a plication device (102 and 10) through a lumen defined by the overtube (Fig. 10-14 and Col. 7 Lines 40-46 where tube 100 and tube 104 each have a lumen), the plication device comprising a pair of movable jaws (Fig. 10-14 where two sets of movable jaws are seen one in part 102 and the other is 18) adapted to engage tissue within the hollow body organ (Fig. 10-14); and forming a tissue fold within the hollow body organ with the plication device (Fig. 10-14). Kortenbach also discloses a flexible tube (12) containing one or more tissue anchors (Col. 7 Lines 58-65 and Col. 8 Lines 1-9).

Kortenbach teaches all the claimed limitations discussed above including that the overtube is an endoscope known in the art (Col. 7 Lines 45-50) however, Kortenbach does not specify the mechanism that provides the endoscope with the movement needed for the procedure. Specifically Kortenbach does not disclose that the overtube comprises a plurality of nested elements having mating contoured surfaces and that the rigid state is caused by imposing a load that clamps the contoured surfaces of adjacent nested elements together nor that that the plication device is advance through the overtube after the overtube has been transitioned to the rigid state.

Crockard discloses a method for performing a medical procedure within a tortuous or unpredictably supported anatomy, the method comprising: advancing an overtube (12 which is an endoscope) comprising a plurality of nested elements (102) having mating contoured surfaces (Fig. 2a-b) within the hollow body organ in a flexible state (Fig. 2a-2b); transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration (Fig. 2c and Col. 5 Lines 28-35).

Crockard further discloses that the endoscope is steered to the site of interest and locked in position and that a medical device is introduced into the overtube, and moved to the site of interest (Abstract and Col. 5 Lines 49-65).

Note that Crockard does not specify that the overtube is locked in a rigid position prior to inserting the plication device. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to lock the endoscope

in the desired position prior to insertion of the plication device since the examiner is taking Official Notice that the locking of the endoscope into a desired location for the procedure is well known in the art in order to prevent undesired movement of the endoscope and plication device while the procedure is being performed. Furthermore, it is well known in the art to first lock the endoscope into position prior to inserting other instrumentation such as the plication device in order to ensure the position of the procedure and clean the area if necessary by using the suction and irrigation of the endoscopes.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kortenbach with an endoscope such as the one taught by Crockard which includes the nestable elements, since the two are well known endoscopes in the art which can be introduced into the patient and steered to the desired location. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the endoscope mechanism as the one taught by Crockard in order to provide the method Kortenbach with the capability of steering and locking the endoscope/overtube in the desired location to properly place the plication device and from the fold on the tissue.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kortenbach with an endoscope/overtube that transitioned to the rigid state prior to insertion of the plication device in view of the teachings of Crockard and the Official Notice above, in order to ensure the position of the procedure and so that movement of the proximal end would

cause little disturbance at the distal end of the device (see Col. 5 Lines 50-53 of Crockard).

Claims 22, 23, 44, and 45:

Kortenbach discloses that endoscopes have viewing mechanism used to visualize the formation of the tissue as described in a prior art endoscope as seen in Col. 1 Lines 59-61.

Kortenbach teaches all the claimed limitations discussed above however, Kortenbach does not specify that the endoscope/overtube used has a visualization element.

Note that Kortenbach uses a well known endoscope in the art which are known to have visualization elements in order for the operator to visualize the hollow body organ and the location of interest.

Crockard discloses visualizing formation of the tissue fold (Col. 3 Lines 1-5) and that the visualizing formation of the tissue fold further comprises visualizing formation with a visualization element advanced through the overtube (Col. 3 Lines 1-5).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kortenbach with a visualization element such as the one taught by Crockard which is advanced through the endoscope/overtube, in order to assist in very accurate positioning of the instrument.

Claims 25 and 47: Kortenbach discloses all the limitations above including that the method wherein the medical procedure comprises endoscopically treating gastroesophageal reflux disease (Col. 10 Lines 15-18), advancing the overtube within a

hollow body organ comprises advancing the overtube through a patient's esophagus and into the patient's stomach (Fig. 10 and Col. 7 Lines 50-55), transitioning the overtube to a bent configuration comprises transitioning the overtube to a bent configuration enabling access to the patient's gastroesophageal junction (Fig. 10-14 and Col. 7 Lines 50-65), and forming a tissue fold comprises forming at least one tissue fold in a vicinity of the patient's gastroesophageal junction (Fig. 10-14 and Col. 7 Lines 50-65).

3. Claims 24, 36, 40-42, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortenbach et al. (7,232,445) in view of Crockard (5,174,276) and further in view of Kortenbach et al. (6,569,085).

Claims 24 and 46:

Kortenbach (7,232,445) in view of Crockard discloses all the limitations discussed in the rejection of claims 21-22 and 43-44 above. However Kortenbach (7,232,445) in view of Crockard does not disclose that the visualization element is coupled to the overtube.

Note that Kortenbach (7,232,445) discloses the use of a well known endoscope in the art to perform the procedure (Col. 7 Lines 45-50) which includes the device of U.S. application 10/931528, now Kortenbach et al. (6,569,085).

Kortenbach (6,569,085) discloses an endoscope/overtube (601) which contains visualization element (601c) which is coupled to the endoscope/overtube as seen in Fig. 14.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kortenbach (7,232,445) in view of Crockard with a visualization element coupled to the overtube/endoscope such as the one taught by Kortenbach (6,569,085), in preventing fluid from entering the lumen of the visualization element the device as well as avoiding unwanted motion of the lens.

Claims 36 and 40-42:

Kortenbach (7,232,445) in view of Crockard discloses all the limitations discussed in the rejection of claims 21-22 and 43-44 above. However Kortenbach (7,232,445) in view of Crockard does not disclose that the device is used to treat a lesion or bleeding area in the organ.

Kortenbach (6,569,085) discloses a method wherein the medical procedure comprises endoscopically treating a bleeding site within a patient's gastrointestinal tract (Col. 5 Lines 1-5) advancing the overtube within a hollow body organ comprises advancing the overtube through the patient's esophagus or colon (Col. 1 Lines 26-30), transitioning the overtube to a state that comprises transitioning the overtube to a configuration enabling access to the bleeding site (Col. 5 Lines 1-10 where the location is where a bleed is occurring or where the tumor is located), and forming a tissue fold comprises forming at least one tissue fold with a plication device advanced through, or coupled to, the overtube, so that the bleeding site is disposed on the tissue fold (Col. 5 Lines 1-30).

Kortenbach (6,569,085) further discloses the method further comprising securing the tissue fold, thereby reducing bleeding from the bleeding site (Col. 5 Lines 1-30) and

the method wherein securing the tissue fold further comprises securing the tissue fold with an anchor assembly (26, 28) (Col. 5 Lines 1-30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the device of Kortenbach (7,232,445) in view of Crockard to treat a bleeding site in the organ such as the method taught by Kortenbach (6,569,085), which would provide the method with a flexible tube with a locking mechanism that would ensure the position of the procedure and so that movement of the proximal end would cause little disturbance at the distal end of the device as well as providing a clip applier that has jaws that compress a clip which assures proper locking and hemostasis of the tissue.

4. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortenbach et al. (7,232,445) in view of Crockard (5,174,276) and Kortenbach et al. (6,569,085) and further in view of Reed (2003/0165887).

Kortenbach 7,232,445) in view of Crockard and Kortenbach (6,569,085) teaches all the claimed limitations discussed above, however S Kortenbach 7,232,445) in view of Crockard and Kortenbach (6,569,085) does not disclose removing the lesion or cancer and removing it with a cutting apparatus such as a snare.

Reed discloses removing the lesion or cancer with cutting apparatus such as a snare [0111].

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kortenbach 7,232,445) in view of Crockard and Kortenbach (6,569,085) with removing the lesion or cancer with a cutting apparatus

such as a snare in view of the teachings of Reed, since the use of cutting tools such as snares are well known biopsy techniques that can be used through the port of endoscopes as well as providing a mechanism to remove damaged tissue.

5. Claims 21, 22, 23, 26-35, 43, 44, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalloo et al (2002/0022851) in view of Crockard (5,174,276).

Claims 21 and 43:

Kalloo discloses a method for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy (Fig. 6-7), the method comprising: advancing an overtube (40) within the hollow body organ in a flexible state (Fig. 6); transitioning the overtube to a desired configuration (Fig. 7 and [0029]); advancing a plication device (70) through a lumen defined by the overtube (Fig. 7 and [0029]), the plication device comprising a pair of movable jaws (68) adapted to engage tissue within the hollow body organ (Fig. 8-9); and forming a tissue fold within the hollow body organ with the plication device (Fig. 10-11). Kalloo also discloses a flexible tube (the tube of 70) containing one or more tissue anchors (contains anchor 68 which has the two jaws).

Kalloo teaches all the claimed limitations discussed above including that the overtube is an endoscope however, Kalloo does not specify the mechanism that provides the endoscope with the movement needed for the procedure. Specifically Kalloo does not disclose that the overtube comprises a plurality of nested elements having mating contoured surfaces and that the rigid state is caused by imposing a load

that clamps the contoured surfaces of adjacent nested elements together nor that that the plication device is advance through the overtube after the overtube has been transitioned to the rigid state.

Crockard discloses a method for performing a medical procedure within a tortuous or unpredictably supported anatomy, the method comprising: advancing an overtube (12 which is an endoscope) comprising a plurality of nested elements (102) having mating contoured surfaces (Fig. 2a-b) within the hollow body organ in a flexible state (Fig. 2a-2b); transitioning the overtube to a rigid state by imposing a load that clamps the contoured surfaces of adjacent nested elements together to thereby substantially fix the shape of the overtube in any desired configuration (Fig. 2c and Col. 5 Lines 28-35).

Crockard further discloses that the endoscope is steered to the site of interest and locked in position and that a medical device is introduced into the overtube, and moved to the site of interest (Abstract and Col. 5 Lines 49-65).

Note that Crockard does not specify that the overtube is locked in a rigid position prior to inserting the plication device. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to lock the endoscope in the desired position prior to insertion of the plication device since the examiner is taking Official Notice that the locking of the endoscope into a desired location for the procedure is well known in the art in order to prevent undesired movement of the endoscope and plication device while the procedure is being performed. Furthermore, it is well known in the art to first lock the endoscope into position prior to inserting other

instrumentation such as the plication device in order to ensure the position of the procedure and clean the area if necessary by using the suction and irrigation of the endoscopes.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kalloo with an endoscope such as the one taught by Crockard which includes the nestable elements, since the two are well known endoscopes in the art which can be introduced into the patient and steered to the desired location. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the endoscope mechanism as the one taught by Crockard in order to provide the method of Kalloo with the capability of steering and locking the endoscope/overtube in the desired location to properly place the plication device and from the fold on the tissue.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Kalloo with an endoscope/overtube that transitioned to the rigid state prior to insertion of the plication device in view of the teachings of Crockard and the Official Notice above, in order to ensure the position of the procedure and so that movement of the proximal end would cause little disturbance at the distal end of the device (see Col. 5 Lines 50-53 of Crockard).

Claims 22 and 44: Kalloo discloses visualizing formation of the tissue fold ([0022]).

Claims 24 and 46: Kalloo discloses that visualizing formation of the tissue fold further comprises visualizing formation with a visualization element coupled to the overtube ([0022] where the components of the visualization means have to be coupled to the

distal end and the proximal end of the overtube) Endoscopes contain a lens at the end of the image channel which is coupled to the end so there is no fluid going into the rest of the device as well as to avoid unwanted motion of the lens.

Claims 26: Kalloo discloses that the medical procedure comprises endoscopically performing gastric reduction ([0019]), advancing the overtube within a hollow body organ comprises advancing an overtube through a patient's esophagus and into the patient's stomach (Fig. 6), transitioning the overtube to a state comprises transitioning the overtube to a state in a desired configuration within the patient's stomach (Fig. 7 and [0029]), and forming a tissue fold (Fig. 7-11). Kalloo further discloses a plurality of folds performed in a gastric reduction procedure (Fig. 11).

Claim 27: Kalloo discloses that the method further comprising approximating and securing the plurality of tissue folds ([0033]), thereby partitioning the patient's stomach into at least first (the pouch at the base disclosed in paragraph [0033]) and second chambers (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]) over at least a portion of the stomach.

Claim 28: Kalloo discloses that forming, approximating and securing a plurality of tissue folds further comprises: forming, approximating and securing a first plurality of tissue folds in a first plane (the first plane is one side of the periphery of the stomach seen in Fig 7); and forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane (the second plane is the opposing side of the first plane in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two planes together), wherein

the first plane and the at least one additional plane are substantially parallel to one another.

Claim 29: Kalloo discloses that partitioning the stomach into first and second chambers further comprises partitioning the stomach into a first lumen (the first chamber disclosed as the pouch at the base of the esophagus has a lumen for receiving the food and digesting it ([0033])) and a second chamber (the collapsed/closed off portion of the stomach disclosed in paragraph [0033]).

Claim 30: Kalloo discloses that partitioning the stomach into a first lumen and a second chamber further comprises partitioning the stomach such that the patient's gastroesophageal junction only communicates with the first lumen ([0033] where the pouch is at the base of the esophagus in order to receive the food and digest it).

Claim 31: Kalloo in view of Crockard discloses the claimed invention except for the first lumen having a volume in the range of 10-50 cm³. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a volume in the range of 10-50 cm³ on the first lumen, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 32: Kalloo discloses that forming a plurality of tissue folds further comprises forming a plurality of tissue folds inferior to the patient's gastroesophageal junction (Fig. 7 where the clip is being placed below the esophagus junction).

Claim 33: Kalloo discloses that forming a plurality of tissue folds further comprises forming a plurality of tissue folds having at least one tissue fold from an anterior

segment of the patient's stomach (the anterior segment is one side of the periphery of the stomach seen in Fig 7) and at least one tissue fold from an opposing posterior segment of the patient's stomach (the posterior segment is the opposing side of the anterior segment in Fig. 7 where the rope is attached to the wall of the stomach in both sides in order to enclose a portion of the stomach by bringing the two segments together).

Claim 34: Kalloo discloses that forming a plurality of tissue folds within a patient's stomach comprises forming and securing a plurality of tissue folds disposed at substantially randomly selected locations to reduce a volume of the stomach (Fig. 11 where there are multiple folds which are randomly placed depending at the location of the rope).

Claim 35: Kalloo discloses that forming a plurality of tissue folds within a patient's stomach comprises forming a plurality of interconnected tissue folds (Fig. 11) around a perimeter of the patient's stomach (the folds are made around a perimeter where the rope is located which is a loop in the stomach that is later closed to separate the stomach into two chambers) with instruments advanced through, or coupled to, the overtube (Fig. 7-11), the method further comprising approximating the plurality of interconnected tissue folds to remodel the stomach to an hourglass profile ([0033]).

Claims 48 and 49: Same as rejection of claims 26-35 above.

Response to Arguments

6. Applicant's arguments with respect to claims 21-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773